

## REMARKS

Claims 1 and 3-45 are pending. Claims 1 and 3-20 are currently under consideration and claim 2 has been canceled. Claims 21-45 are withdrawn. Claims 3, 5 and 9 are currently amended.

### Claim Objection

The Examiner objected to claim 8 due to inclusion of the acronym EGDMA. Applicants assume the Examiner intended to object to claim 9, since this term is found in claim 9 and not claim 8. Claim 9 has been amended to recite the full chemical name for EGDMA, ethylene glycol dimethacrylate. Support for this amendment is found at least at paragraph [0046] of the application as originally filed.

### 35 USC 112 Rejections

The Examiner rejected claims 1-3 under 35 USC 112, first paragraph, as failing to comply with the written description requirement due to inclusion of the term “monomer that is capable of forming a thermosensitive polymer”.

Applicants point out that the *University of Rochester v. G.D. Searle & Co.* case cited by the Examiner was directed to a case where the claims were to methods of obtaining unknown compounds. The compounds were described in the specification only by functional characteristics and that had not been identified and that had not been demonstrated to exist. In contrast, monomers capable of forming thermosensitive polymers are known and are described in the present specification in terms of chemical and physical properties (see for example paragraphs [0028] to [0031], [0036] and [0037] of the present application).

The “monomer that is capable of forming a thermosensitive polymer” is itself not thermosensitive, but once polymerized in a polymer the monomer imparts thermosensitivity to the polymer. Thermosensitive polymers have known characteristics, including different hydration states above and below a certain temperature, commonly known as the lower critical solution temperature of the polymer, as indicated in paragraphs [0028] and [0030] of the present application. This differential affinity for water imparts swellability characteristics

to the polymers. Thus, present claims 1 and 3 specify a class of compounds that is known and understood in the art.

Applicants also point to paragraphs [0036] and [0037] of the present application, which set out possible monomers that are capable of forming a thermosensitive polymer and which are suitable for use in the presently claimed processes. The Examiner indicated that there is no identifying characteristic provided for the compounds identified in these paragraphs other than the disclosure of the specific compounds as examples of monomers capable of forming thermosensitive polymers. However, given that the general term is known and understood in the art, and that thermosensitive polymers having swellability characteristics relating to a lower critical solution temperature are known and understood, Applicants submit that a skilled person does not require further clarification or identifying features. Accordingly, Applicants submit that a sufficient number of representative species encompassing monomers that are capable of forming thermosensitive polymers is disclosed in the present application.

The Examiner rejected claims 1-4 under 35 USC 112, first paragraph, as failing to comply with the written description requirement on the basis that inclusion of the indistinct term "polymerizable surfactant" would not reasonably convey to a skilled person that the inventors had possession of the claimed invention at the time of filing of the application.

Applicants submit that the precise nature and identity of the polymerizable surfactant is not required to understand the claimed invention of claims 1 and 3-4, and that a skilled person would appreciate this upon reading the present application. A skilled person, upon reading the present application, would appreciate that the role of the polymerizable surfactant is to act as a surfactant and to copolymerize with the monomer capable of forming a thermosensitive polymer and any other comonomer that may be included in the microemulsion. Any surfactant that can copolymerize with the monomer capable of forming a thermosensitive polymer may be used, and the surfactant may be chosen based on the other components included in the microemulsion.

Applicants point out that the term “polymerizable surfactant” is a term understood in the art and is not merely a functional description of desired properties. Polymer chemistry is a developed field and polymerization of polymers including a polymerizable surfactant has been studied extensively. In fact, the Gan et al. reference cited by the Examiner under the current 35 USC 103 rejection uses the terms “non-polymerizable surfactants” and “polymerizable surfactants” in the Introduction section, indicating that these terms are used in the art and are well understood.

Surfactants are a class of compounds that are well known and understood in the art. Polymerization is also a known concept, and describing a surfactant as polymerizable does not render the well-understood term “surfactant” indistinct. If anything, modifying the term “surfactant” with the defining term “polymerizable” serves to clarify which surfactants can be used in the presently claimed processes. A skilled person would understand that a polymerizable surfactant is a surfactant that includes functional groups that allow the surfactant to react with itself or other comonomers in order to form a polymer. The skilled person would also appreciate that the exact functional groups that may be present in the polymerizable surfactant may depend on the comonomers included in the microemulsion with which the surfactant is intended to copolymerize. Accordingly, Applicants submit that the term “polymerizable surfactant” included in claims 1 and 3-4 does not render these claims lacking in written description.

The Examiner rejected claim 2 under 35 USC 112, first paragraph, as failing to comply with the written description requirement due to inclusion of the term “acrylamide derivative”. The Examiner also rejected claim 2 under 35 USC 112, second paragraph, as indefinite due to inclusion of the term “derivative”. Claim 2 has been deleted, rendering these rejections moot.

The Examiner rejected claims 5-7 under 35 USC 112, second paragraph, as indefinite due to inclusion of the term “fluronic68-diacrylate” in claim 5. Fluronic68-diacrylate is a

commercial name used to describe the chemical poly(ethylene oxide)<sub>78</sub>-poly(propylene oxide)<sub>30</sub>-poly(ethylene oxide)<sub>78</sub>-diacrylate. Although a skilled person would readily understand the reference to fluronic68-diacrylate to be a reference to poly(ethylene oxide)<sub>78</sub>-poly(propylene oxide)<sub>30</sub>-poly(ethylene oxide)<sub>78</sub>-diacrylate, to expedite prosecution claim 5 has been amended to replace the term “fluronic68-diacrylate” with its chemical name.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 USC 112, first and second paragraphs.

### 35 USC 103 Rejections

The Examiner rejected claims 1-13 under 35 USC 103 as being unpatentable over cited references Gan et al. in view of Vakkalanka et al.

Applicants respectfully submit that these claims are patentable over the cited references, for at least the following reasons.

Independent claim 1 is directed to a process for preparing a thermosensitive nanoporous polymer comprising polymerizing a microemulsion comprising a first monomer that is capable of forming a thermosensitive polymer and a polymerizable surfactant.

Claim 1 thus specifies copolymerization of a monomer that is capable of forming a thermosensitive polymer together with a polymerizable surfactant from a microemulsion and that the resulting polymer is both nanoporous and thermosensitive.

As indicated by the Examiner, the Gan et al. reference does not describe or suggest inclusion of monomers capable of forming a thermosensitive polymer in the microemulsion.

However, the Examiner cited the Gan et al. reference in combination with the Vakkalanka reference, arguing that the Vakkalanka reference describes the preparation of hydrogels from a mixture that includes acrylic acid, 2-hydroxyethyl methacrylate and N-

isopropylacrylamide (NIPAAm) and that inclusion of the NIPAAm provided significant temperature sensitivity.

The Vakkalanka reference describes polymerization of hydrogels using conventional aqueous polymerization methods and therefore does not describe inclusion of a polymerizable surfactant.

Furthermore, the Vakkalanka reference teaches away from the presently claimed methods and a skilled person would be directed not to copolymerize a monomer that is capable of forming a thermosensitive polymer together with a polymerizable surfactant, as specified in the presently claimed methods. That is, the portion of the Vakkalanka reference to which the Examiner points in fact describes that block copolymer hydrogels (i.e. polymerized using blocks of preformed polyNIPAAm) have significant temperature sensitivity (see Summary, page 221 of the Vakkalanka reference) rather than hydrogels copolymerized as random copolymers. In fact, Vakkalanka indicates that the swelling ratio dependence on temperature is significantly more prominent for block terpolymers than for the corresponding random terpolymers. In Vakkalanka, the random terpolymers exhibited only very slight swelling above polymers containing no NIPAAm.

The Vakkalanka reference indicates that for copolymers made with monomers of NIPAAm, the amount of NIPAAm must be significant in order for the copolymer to exhibit any thermosensitivity, and that to overcome this problem, polymers of PNIPAAm (PNIPAAm) are first formed and then the PNIPAAm is used as blocks in the formation of hydrogels (see for example the paragraph bridging pages 221 and 222 of the reference). The random copolymers formed from solutions containing even as much as 10% of monomeric NIPAAm demonstrated very low temperature sensitivity, which was described as a “very small change” in terms of swelling in response to temperature changes (see first full paragraph on page 224 of the Vakkalanka reference). This is in contrast to the block copolymers polymerized using PNIPAAm, which showed “significantly higher degree of temperature sensitivity” (see paragraph bridging pages 224 and 225 of the Vakkalanka reference).

The Vakkalanka reference discloses therefore that in order to form a hydrogel copolymer using conventional copolymerization methods that demonstrates desirable levels of thermosensitivity, monomers capable of forming thermosensitive polymers should not be used, and polymeric stretches of a thermosensitive polymer, such as polymeric NIPAAm, should be used in the copolymer instead, and accordingly teaches away from the presently claimed methods.

The Gan et al. reference also discloses that the form of the polymerization solution affects the final structure of the resulting polymer (see first paragraph of the Introduction section of the Gan et al. reference).

Applicants submit that the combination of Gan et al. and Vakkalanka et al. do not render current claim 1 unpatentable. Assuming that the skilled person would want to modify the Gan et al. reference to obtain a thermosensitive polymer, the skilled person would be led by Vakkalanka et al. to copolymerize a hydrogel using segments of pre-formed thermosensitive polymer in order to obtain a block copolymerized hydrogel having significant degree of thermosensitivity. Copolymerization of monomers capable of forming a thermosensitive polymer from conventional aqueous solutions to form hydrogels is disclosed as providing minimal if any thermosensitivity to the polymers and is thus discouraged by the Vakkalanka et al. reference.

Further, the skilled person, in any event, would not combine the Gan et al. and Vakkalanka et al. references. The Vakkalanka reference promotes increasing local NIPAAm concentration (see second full paragraph on page 224 of the Vakkalanka et al. reference). In contrast, copolymerization from the microemulsion in the presently claimed methods results in pore formation, which would effectively decrease local NIPAAm concentration, rather than increase it, as directed by Vakkalanka et al.

Furthermore, there is no suggestion in the Gan et al. reference that inclusion of a monomer capable of forming a thermosensitive polymer would result in a nanoporous polymer having thermosensitive properties. Likewise, there is no suggestion in Vakkalanka et al. that use of a microemulsion copolymerization method and inclusion of a polymerizable surfactant would have the opposite effect of imparting thermosensitivity to the resulting copolymer, in contrast to the findings of Vakkalanka et al. Rather, there is a direction in Vakkalanka that monomers should not be used and that the monomers should be pre-homopolymerized prior to inclusion in the copolymer solution in order to provide a resulting copolymer that exhibits thermosensitivity.

Thus, Applicants submit that there is no reasonable basis for a skilled person, having regard to the disclosures of the Gan et al. reference and the Vakkalanka et al. reference, to expect that addition of a monomer capable of forming a thermosensitive monomer into a copolymerization reaction within a microemulsion would provide a nanoporous polymer that was thermosensitive or to even combine the two references, given the disclosures of these cited references.

Claims 3-20 depend directly or indirectly from independent claim 1 and thus these claims incorporate all of the features of claim 1. For at least the reasons given above, Applicants submit that dependent claims 3-20 are also patentable having regard to the combination of Gan et al. and Vakkalanka et al.

The Examiner further rejected claims 14-20 under 35 USC 103 as unpatentable over Gan et al., Vakkalanka et al. and further in view of Liu et al. Specifically, the Examiner is of the opinion that it would have been obvious to a skilled person to optimize the amounts of 2-hydroxyethyl methacrylate,  $\omega$ -methoxy poly(ethylene oxide)<sub>40</sub> undecyl- $\alpha$ -methacrylate and water in order to control the pore size of the polymeric material.

Claims 14-20 each depend indirectly from claim 1 and incorporate all of the features of independent claim 1. Liu et al. does not compensate for the defect in the combination of

the Gan et al. reference and Vakkalanka et al. reference in that it does not suggest that a monomer capable of forming a thermosensitive polymer, if included in the Gan et al. method, would impart thermosensitivity to the resulting polymer. Thus, for the same reasons above, Applicants submit that claims 14-20 are patentable over the combination of Gan et al., Vakkalanka et al. and Liu et al.

Additionally, Applicants point out that in claims 14-20, the amounts specified for NIPPAm and for methyl methacrylate vary among each of claims 14-20, and are particular specified concentrations. Liu et al. does not suggest inclusion of a monomer capable of forming a thermosensitive polymer, and Vakkalanka et al. discloses that the ratio and amount of these components within the microemulsion would influence local concentrations of NIPPAm monomers, which can significantly undermine the thermosensitivity of the resulting copolymer. Applicants submit that the precise amounts of these two comonomer elements as currently claimed in claims 14-20 would not be obvious in view of the cited references, even if combined.

As well, Applicants submit that even if, *arguendo*, a skilled person wanted to vary the amounts of 2-hydroxyethyl methacrylate,  $\omega$ -methoxy poly(ethylene oxide)<sub>40</sub> undecyl- $\alpha$ -methacrylate and water in order to control pore size, none of the references, alone or in combination, direct a skilled person to the specific proportions of each of these components, in combination with the specified amounts of the NIPPAm and methyl methacrylate components, as set out in each of present claims 14-20.

Thus, in addition to the comments provided above for the combination of Gan et al. and Vakkalanka et al., Applicants submit that further combination of the Liu et al. reference does not render the presently claimed processes of claims 14-20 as obvious.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 USC 103.



**Conclusion**

It is believed no new matter has been added by the amendments.

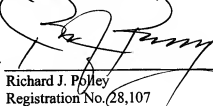
Applicants respectfully request entry of this amendment, favourable consideration and withdrawal of the rejections.

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Respectfully submitted,

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